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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,868

12/03/2004

Dorothy French

P1959R1

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7590

09/29/2006

GENENTECH, INC.

1 DNA WAY

SOUTH SAN FRANCISCO, CA 94080

EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/516,868

Applicant(s)

FRENCH ET AL.

Examiner

Kelaginamane T. Hirianna

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/05;2/06;7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 07/05/2006 in response to office action mailed on 01/05/2006 has been acknowledged.

Claims 1-9 are cancelled.

Claims 10-11 are amended.

Claims 12-19 are newly added.

Claims 10-19 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 101

(I). Claim rejection under 35 USC § 101 of the claims 1-11 as drawn to non-statutory subject matter are hereby withdrawn in view of the cancellation of claims 1-9 and amendments of claims 10-11 to state "mouse" instead of 'mammal'.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11 recite the phrase 'a phenomenon associated with' which makes the claim indefinite. It is unclear what is the phenomenon associated with hepatocellular

carcinoma in this context. A remedial measure would require replacing of said phrase with an observed phenomenon by 'name'.

Claims 10-19 recite the term 'acquires' or 'acquiring' which makes the claims indefinite as it implicates transfer of an already existing 'condition' or 'a disease' from another. A remedial measure would require replacing said term with alternate terms such as for example 'develops'.

Claim 10-11 and 19 recites the limitation 'determining the effect of said agent'. There is insufficient antecedent basis for this limitation in the claim. It is not clear what 'the effect' refers to in this context of invention as claimed.

Claims 10-19 are indefinite because the claims are generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Following language has been suggested:

(Claim X): A method of screening for biologically active agents that modulate hepatocellular carcinoma development, the method comprising administering a candidate agent to a transgenic mouse having a genome comprising a stably integrated transgene encoding FGF19 and operably linked to a promoter, wherein said transgene results in said mouse developing hepatocellular carcinoma characterized by increased proliferation of pericentral hepatocytes and elevated levels of alpha-fetoprotein as compared with a control non-transgenic mouse and determining the extent of development of hepatocellular carcinoma as indicated by the extent of proliferation of pericentral hepatocytes or the levels of alpha-fetoprotein in said transgenic mouse as compared to a non-transgenic control mice.

Claim Rejections - 35 USC § 112 (First Paragraph)

(II). Claim rejection under 35 USC § 112 first paragraph (written description) of claims 1-11 as failing to comply with the written description requirement for the reasons of record as set forth in the previous office action is hereby withdrawn in view of

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applicants cancellation of claims 1-9 and amendment to claims 10-11 to recite "mouse" instead of "mammal".

(III). Claim rejection under 35 USC § 112 first paragraph (enablement) of claims 1-11 as lacking full enablement for the reasons of record as set forth in the previous office action is hereby withdrawn in view of applicants cancellation of claims 1-9 and amendment to claims 10-11 to recite "mouse" instead of "mammal".

Claim Rejections - 35 USC § 102

(III). Claim rejection under 35 USC § 102 of claims 1-9 as not patentable over prior art of record (***Pub No. US 2002/00442367 A1***) for the reasons of record as set forth in the previous office action is hereby withdrawn in view of applicants cancellation of claims 1-9.

(IV). Claim rejection under 35 USC § 102 of claims 1-11 as not patentable over prior art of record (Nicholes et al.,) for the reasons of record as set forth in the previous office action is hereby withdrawn in view of applicants cancellation of claims 1-9 and further the rejection of claims 10-11 on the same is withdrawn in view of applicants submission of 37 CFR 1.132 in which the applicant Dr. French states that she and co-author Jean-Philippe Stephen also a co-inventor on the application are the only authors of the Nicholes paper who inventively contributed to the subject matter of the Nicholes paper.

Claim Rejections - 35 USC § 103

(V). Claim rejection under 35 USC § 103 of claims 1-11 as upatentable over prior art of record (Nicholes et al., in view of Bosteine et al) for the reasons of record as set forth in the previous office action is hereby withdrawn in view of applicants cancellation of claims 1-9 and further the rejection of claims 10-11 on the same is withdrawn in view of applicants submission of 37 CFR 1.132 in which the applicant Dr. French states that she and co-author Jean-Philippe Stephen also a co-inventor on the application are the only

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authors of the Nicholes paper who inventively contributed to the subject matter of the Nicholes paper.


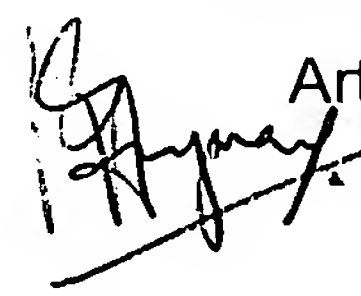
Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hirianna* whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Friday from 9 AM-5PM. Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst *Victor Barlow*, whose telephone number is (571) 272-0506. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Dave Nguyen*, may be reached at (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hirianna
Patent Examiner

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SUMESH KAUSHAL, PH.D.
PRIMARY EXAMINER